

REMARKS

With entry of this amendment, claims 53-56 are pending in the application. By this amendment, claims 53 and 55 and 56 have been amended and new claims 57-62 have been added. Claims 1-52 were previously canceled without prejudice, and Applicants continue to reserve the right to pursue the subject matter of these canceled claims in one or more related applications. All of the amendments herein are fully supported by the disclosure, and no new matter has been added to the application.

Impropriety of Final Rejection

As a preliminary matter, it is clear that the present Office Action has been improperly designated as final. In particular, the Office for the first time has rejected claims 54 and 56 under 35 USC § 112, second paragraph as allegedly indefinite for use of the term “concentration.” As a result, Applicants have not previously had a chance to address this ground of rejection. In accordance with Office rules and policies, it is therefore respectfully urged that the the finality of the present Office Action be reconsidered and withdrawn.

Patentability Under 35 USC § 112, First Paragraph

Claims 53-56 are rejected under 35 USC § 112 for alleged failure to comply with the written description requirement. Specifically, the Office contends that the term “organic eluent” is allegedly not supported by the specification--on the asserted basis that “[t]here is no disclosure that any and/all organics are applicable as eluents in the instant process.”

Applicants respectfully traverse the foregoing rejection and submit that the disclosure adequately conveys the subject matter of the invention in a manner sufficient to fulfill the written description requirements of 35 USC § 112, based on the facts and reasoning set forth herein below, and as presented in the Amendment dated February 22, 2005 (“Prior Amendment”), and in view of the entire record in this application.

Applicants’ disclosure clearly teaches that a range of useful organic eluents can be effectively employed within the subject method in a manner that would have been readily

understood by those of ordinary skill in the art. In particular, the specification teaches (e.g., beginning at p. 7, paragraph [0035]) that:

The preferred eluent is a hydrocarbon solvent adjusted in polarity with a miscible polar organic solvent.” Preferably, the organic eluent contains a non-polar, hydrocarbon solvent present in about 95% to about 99.5% (volume/volume) and a polar organic solvent present in about 5 to about 0.5% (volume/volume). In a preferred embodiment, the hydrocarbon solvent is hexane and the miscible polar organic solvent is isopropylamine.

Applicants therefore maintain that the instant rejection is overcome based on the record, and in particular the express teachings of Applicants’ disclosure. However, for the sole purpose of advancing the instant Application to allowance, claims 53 and 55 have been amended, for clarity and without intent nor effect to limit the claims, to recite that the organic eluant comprises a hydrocarbon solvent adjusted in polarity with a miscible polar organic solvent. Support for these amendments can be found in the specification, e.g., beginning on page 7, paragraph [0035], a portion of which is quoted above. Applicants specifically reserve the right to pursue any cancelled or withdrawn subject matter as supported by the disclosure in one or more related applications.

In view of the foregoing, the rejection of claims 53-56 under 35 USC § 112, first paragraph is respectfully submitted to be overcome.

Patentability Under 35 USC § 112, Second Paragraph

Claims 53-56 are rejected under 35 USC § 112, second paragraph as allegedly indefinite for use of the word “eluent.” In addition, as noted above, that Office has levied an entirely new ground of rejection by rejecting claims 54 and 56 under 35 USC § 112, second paragraph as allegedly indefinite for use of the term “concentration.” In making these rejections, the Office refers to the preferred eluents set forth in the specification as “examples only.” Similarly, the Office refers to the term “hydrocarbon solvent” set forth in the specification as an “example” and takes the position that this term “does not sufficiently identify the eluants.”

Applicants respectfully traverse the foregoing rejections and submit that the use of the term "eluent" in the claims fully satisfies the requirements of 35 USC § 112, second paragraph, based on the facts and reasoning set forth herein below, and as presented in the Amendment dated February 22, 2005 ("Prior Amendment"), and in view of the entire record in this application.

It appears that the Office has not fully considered the nature of Applicants' invention. In one principal aspect, Applicants have shown that (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane can be successfully resolved from its racemic mixture using a chiral polysaccharide stationary phase. Based on these teachings regarding the chemical structure of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane and the characteristics of the chiral polysaccharide stationary phase, one of ordinary skill in the art would be able to choose additional organic eluents for use in this process. The Office takes the position that terms such as "organic eluant" and "hydrocarbon solvent" are overly broad and specifically states that "[t]he term "hydrocarbon" embraces the entire textbook of organic chemistry and does not sufficiently identify the eluents." However, one of ordinary skill in the art, apprised of Applicants' teachings regarding the chemical structure of (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane and the characteristics of the chiral polysaccharide stationary phase, would understand that a finite assemblage of organic eluants and hydrocarbon solvents would be useful in the claimed process, and would be able to choose other appropriate organic eluants and hydrocarbons without undue experimentation. Similarly, one of ordinary skill in the art would be able to choose useful concentrations and other process parameters following Applicants' teachings without undue experimentation.

Applicants therefore respectfully submit that the instant disclosure fully supports the scope of the pending claims, and in particular that the (-)-1-(3,4-dichlorophenyl)-3-azabicyclo[3.1.0]hexane can be successfully resolved from its racemic mixture using a chiral polysaccharide stationary phase, without having to specify an unduly limiting list of particular organic eluents and concentration techniques. However, as discussed above, the claims have been amended and now indicate that the organic eluant comprises a hydrocarbon solvent adjusted in polarity with a miscible polar organic solvent.

Therefore, withdrawal of the rejection of claims 53-56 under 35 USC § 112, second paragraph is earnestly solicited.

Patentability Under 35 USC § 103

Claims 53-56 are rejected under 35 USC § 103 as allegedly unpatentable over Miller et al., J. Chrom. A, (1999) Vol. 865, pp. 211-226, for reasons as set forth in the prior Office Action dated September 21, 2004.

Applicants respectfully traverse the foregoing grounds of rejection and submit that the subject matter of claims 53-56 is neither disclosed nor suggested by Miller et al., based on the facts and reasoning set forth herein below, and as presented in the Amendment dated February 22, 2005 ("Prior Amendment"), and in view of the entire record in this application.

The Office has overlooked significant deficiencies and limitations in the disclosure of Miller et al., along with substantial differences between the Miller et al. disclosure and the presently claimed invention. Miller et al. reports preparative chromatographic resolution of enantiomers of six different compounds using polysaccharide chiral stationary phases. Significantly, the Miller et al. publication fails to disclose the structure of any of these compounds. This is of critical importance in this field of art, since the preparative HPLC separation conditions for the six different compounds were quite different. In particular: (1) compounds 1-4 utilized a one step process while compounds 5 and 6 utilized a two step process; (2) compounds 1 and 5 utilized an acetonitrile mobile phase, compound 2 utilized an ethanol mobile phase, compound 3 utilized a methanol mobile phase, compound 4 utilized a methanol/ethanol (10:90, v/v) mobile phase, and compound 6 utilized an acetonitrile-0.1% acetic acid mobile phase. Because no structures of the compounds are provided, one of ordinary skill in the art would be unable, or would at best require undue experimentation, to predict what separation conditions set forth in Miller et al. might be useful for other specific compounds.

Furthermore, all of the separations reported by Miller et al. and noted above utilized a polar organic phase. In contrast, the currently claimed invention employs a distinct, mobile phase comprising a hydrocarbon solvent adjusted in polarity with a

miscible polar organic solvent. Indeed, as seen at page 212, left column of Miller et al., the authors specifically contrasted their methods with those that employ hydrocarbon based mobile phases.

In view of the foregoing, it is clear that the Office has not met its burden of providing direct scientific evidence that Miller et al. teaches, or practically motivates, the independent discovery of every element and limitation in the claims presented for review. Therefore, Applicants respectfully request that the rejection of claims 53-56 under 35 USC § 103 as allegedly unpatentable over Miller et al., J. Chrom. A, (1999) Vol. 865, pp. 211-226, be withdrawn.

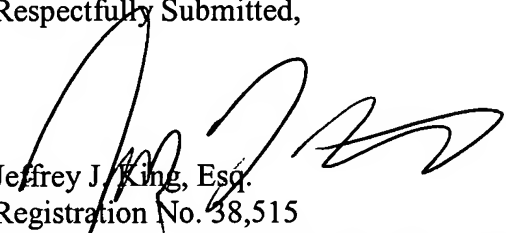
CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (425) 455-5575.

Respectfully Submitted,

Dated this 3rd day of August, 2005



Jeffrey J. King, Esq.
Registration No. 38,515
GRAYBEAL JACKSON HALEY, LLP
155 – 108TH Avenue N.E. – Suite 350
Bellevue, Washington 98004-5973
Telephone: (425) 455-5575
Facsimile: (425) 455-1046